UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

STEVEN B. CHRISTIANSEN, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

SPECTRUM PHARMACEUTICALS, INC., THOMAS J. RIGA, FRANCOIS J. LEBEL, NORA E. BRENNAN,

Defendants.

Case No. 1:22-cv-10292 (VEC)

Consolidated with

Case No. 1:22-cv- 10677 (VEC); Case No. 1:23-cv-00767 (VEC)

JURY TRIAL DEMANDED

CLASS ACTION

CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

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Dated: May 26, 2023

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Lead Plaintiff Steven Christiansen ("Plaintiff"), on behalf of himself and a class of similarly situated investors, by and through Plaintiff's counsel, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. The investigation of counsel included, among other things: 1) a review of Spectrum Pharmaceuticals, Inc.'s ("Spectrum" or the "Company") public filings with the United States Securities and Exchange Commission ("SEC"); 2) press releases issued by the Company, and media, news and analyst reports about the Company; 3) Spectrum quarterly earnings conference calls, and investor conferences with Company executives, and analysts and investors; 4) information based on consultation with experts in loss causation and economic loss; 5) publicly available information relating to the September 22, 2022 virtual meeting of the Oncologic Drugs Advisory Committee of the United States Food and Drug Administration's Center for Drug Evaluation and Research (defined below), including the transcript of the virtual meeting and the FDA's briefing document (defined below); and 6) other publicly available data, including, but not limited to, publicly available trading data relating to the price and trading volume of Spectrum's common stock. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. OVERVIEW OF THE CLAIMS

1. This is a securities class action on behalf of all purchasers of Spectrum common stock during the period March 17, 2022 through September 22, 2022, inclusive (the "Class Period"), who were damaged thereby (the "Class"). The claims asserted in this consolidated action (the "Action") are alleged against Spectrum, Thomas J. Riga ("Riga"), the Company's President and Chief Executive Officer ("CEO") and a member of the Company's board of directors, Francois J. Lebel ("Lebel"), the Company's former Executive Vice President ("EVP") and former Chief Medical Officer ("CMO"), and Nora E. Brennan ("Brennan"), the Company's EVP and Chief

Financial Officer ("CFO") and former member of the Company's board of directors, and arise under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5, promulgated thereunder.

- 2. Before and during the Class Period, Spectrum purported to be a biopharmaceutical company focused on acquiring, developing, and commercializing novel and targeted oncology therapies. The Company focused on development of poziotinib, or "pozi", a drug under investigation for the treatment of previously treated patients (so-called second-line patients) with non-small cell lung cancer ("NSCLC") with certain genetic mutations, including HER2 exon 20 insertion mutations, which represent 2-3% of NSCLC patients. Pozi is administered orally and purports to be an inhibitor of certain cellular activity linked to cellular growth (called a tyrosine kinase inhibitor, or TKI) in NSCLC.
- 3. Before any new drug can be marketed and sold commercially in the U.S., the United States Food and Drug Administration ("FDA") requires that the drug undergo clinical trials involving three phases of human testing, with each phase involving increasingly larger patient pools. Typically, Phase 1 trials test the safety, dose tolerance, and other properties of the drug; Phase 2 trials seek to gather information about efficacy, optimal dosage levels, adverse effects, and safety risks; and Phase 3 trials are designed to gather further efficacy and safety information used to evaluate a drug's overall benefit/risk profile. In a Phase 3 trial involving anti-cancer drugs, the drug candidate is typically compared to a standard, FDA-approved treatment for the target disease to verify clinical benefit or lack of benefit, and study patients are randomly assigned to receive the drug candidate or the standard of care treatment. After completion of all three clinical trial Phases, if the data indicates that the drug is safe and effective, a new drug application ("NDA") can be filed with the FDA requesting approval to market the new drug as a treatment for the target

disease.

- 4. However, in cases where a drug candidate treats a serious condition and fills an unmet medical need, the FDA developed the Accelerated Approval ("AA") pathway for earlier approval of drugs that demonstrate an effect on an endpoint (a measurement of benefit) reasonably likely to predict clinical benefit. AA is typically based on Phase 2 study data results. For a drug candidate granted approval under the AA pathway, the FDA has postmarketing requirements ("PMR"), which are typically additional studies or clinical trials designed to confirm or verify clinical benefit. PMRs are typically one or more Phase 3 randomized controlled studies, referred to as confirmatory studies or trials. FDA guidance provides that at the time AA is granted, a Phase 3 confirmatory trial should already be underway because Phase 3 confirmatory trials that are in progress at the time AA is granted are more likely to result in a timely verification of benefit, and mitigate the risks that patients are exposed to undue risks by an ineffective drug granted AA.
- 5. In or around October 2017, Spectrum commenced a clinical development program for pozi that included a Phase 2 study of pozi's efficacy and safety, referred to as Cohort 2. Cohort 2 comprised 90 patients with previously treated locally advanced or metastatic NSCLC with HER2 exon 20 insertion mutations and all patients were to be treated with 16 mg of pozi QD ("QD" is once per day). In a July 27, 2020 press release, Spectrum stated that Cohort 2 had met its primary endpoint (27.8% of patients experienced reduction in tumor size), and in December 2020, Spectrum disclosed that the FDA allowed the Company to file an NDA based on the Cohort 2 study data results under the AA pathway.
- 6. On November 24, 2021, Spectrum completed its submission of the NDA for pozi at a 16 mg QD dose in patients with previously treated NSCLC with HER2 exon 20 insertion mutations (the "Pozi NDA"), and sought AA for the 16 mg QD dose based on the Phase 2 study

data results from Cohort 2. Spectrum's PMR, or Phase 3 confirmatory trial, was called the PINNACLE Study.

- 7. In November 2021, during Spectrum's earnings conference call with investors announcing the Company's third quarter 2021 financial results, an analyst asked Defendant Lebel, the Company's CMO, "what confirmatory study are you committing to in terms of design? Because obviously you need to do that as part of the [AA]?" In response, Defendant Lebel stated:
 - . . . we're in discussion with the [FDA] regarding this, and we clearly have developed a PMR [(the PINNACLE Study)]. And when you file the NDA, you have to have a PMR essentially underway and so we absolutely intend to do that. But obviously, want to make sure we're in complete agreement . . . as to the nature of the PMR. So I'm not going to go any further on that, but it's probably a randomized controlled study . . . And we'll need to define that with the [FDA] and probably quite soon, you will be able to see what we're doing.
- 8. In February 2022, Spectrum told investors that the FDA had accepted the Pozi NDA for review, that under the Prescription Drug User Fee Act ("PDUFA"), the FDA set November 24, 2022 (referred to as the PDUFA date) as the date by which the FDA would approve the Pozi NDA, reject it, or issue a complete response letter ("CRL"), and that the "FDA [had] reiterated [to Spectrum] the importance of having the confirmatory trial [(the PINNACLE Study)] substantially enrolled at the time of [AA]...".
- 9. The Class Period begins on March 17, 2022, when, during Spectrum's conference call with investors and analysts to discuss the Company's fourth quarter 2021 and full-year 2021 financial results, Defendant Riga represented that "we have learned to optimize" the dosage for pozi. Dose optimization data identifies a dosage that provides optimal balance of efficacy and safety needed to maximize the chances of a successful outcome in a Phase 3 study.
 - 10. Defendant Riga's representation that Spectrum had learned to "optimize" the

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¹ The FDA will send a CRL if it determines that it will not approve an application in its present form and will describe all of the specific deficiencies that the FDA has identified in an application.

dosage for pozi was materially false and misleading because, unknown to investors, during meetings with Defendants Lebel and/or Riga before the Class Period, the FDA repeatedly told Defendants Lebel and/or Riga that Spectrum's dosing data were inadequate and that additional data and studies were needed to determine whether Spectrum's dose selection for pozi was optimized.

- 11. The sticking point for the FDA was that while patients in Cohort 2 were treated with 16 mg QD and the Pozi NDA sought AA to treat patients with a 16 mg QD dose, Defendants Riga and/or Lebel proposed to treat patients in the PINNACLE Study with a different dosage regimen (8 mg BID (twice per day)) in an effort to mitigate negative side effects observed in Cohort 2 while maintaining efficacy. The incongruent dosing schedules troubled and concerned FDA officials. While Spectrum had submitted with the Pozi NDA dosing data from a Phase 1 study and additional dosing data, including from an ongoing pozi exploratory trial (Cohort 5) in which patients were treated with 6 or 8 mg BID, or 10 mg QD, the FDA repeatedly told Defendants Riga and/or Lebel that the data were inadequate and that additional dosing data and studies were required to determine the optimal dose for further evaluation in the PINNACLE Study. The FDA also repeatedly expressed concerns to Defendants Lebel and/or Riga that pozi's efficacy was low and did not represent an advantage to patients over other approved therapies, and that the safety profile demonstrated a high level of toxicity, requiring a large number of dose reductions and drug interruptions. In light of the FDA's concerns, the FDA informed Defendants Riga and/or Lebel that additional data were needed to determine whether the pozi dose was optimized for further evaluation in the PINNACLE Study. As revealed after the Class Period by the FDA, Spectrum's failure to optimize the dosage was a "fatal flaw" in the development of pozi.
 - 12. Also during the March 17, 2022 conference call, Defendant Lebel stated that

Spectrum would disclose the design and details of the PINNACLE Study after the first patient was enrolled.

13. Then, on May 12, 2022, Defendants Riga and Lebel disclosed the design and details of the PINNACLE Study, and represented that patients were enrolling in the PINNACLE Study:

A study for poziotinib has been initiated to confirm the clinical benefit seen in Cohort 2, as required for an accelerated approval. The trial, Study SPI-POZ-301 (PINNACLE), is designed to enroll 268 patients with previously treated NSCLC harboring HER2 exon 20 mutations. Patients are being randomized 2-to-1 into one of two treatment arms using 8mg of poziotinib orally administered BID (twice daily) versus 75mg/m2 of docetaxel administered intravenously every three weeks. The primary endpoint will be Progression Free Survival.

(Emphasis added).

- 14. Also on May 12, 2022, during a Spectrum conference call with investors, an analyst asked Defendants Riga and Lebel "how do you reconcile a full approval in a different dose [16 mg QD] with the [AA] with a sort of different dosing schedule [(8 mg BID])?" Defendant Riga responded "we believe that 16 QD is a safe and effective dose and obviously aligned with FDA on the confirmatory study to go with the 8-milligram BID." (Emphasis added).
- 15. Defendants' representations were materially false and misleading because they created the false impression that the PINNACLE Study was enrolling patients and that PINNACLE was on track to be substantially enrolled by November 24, 2022 (the PDUFA date), when, in fact, no patients had enrolled, and that Defendants and the FDA were aligned concerning the design of the PINNACLE Study to treat patients at the 8 mg BID dose, which was not true. Unknown to investors, in light of the FDA's concerns about the inadequate dose optimization data, and pozi's efficacy and safety data, the FDA did not agree with Defendants on the design of the PINNACLE Study and had warned Defendants Lebel and/or Riga that proceeding with PINNACLE at 8 mg BID was at their own risk. Unknown to investors, as of May 12, 2022, no patients had enrolled in the PINNACLE Study.

16. As later revealed at a public meeting of the FDA's Oncologic Drugs Advisory Committee ("ODAC")² on September 22, 2022 at the end of the Class Period to discuss the Pozi NDA and to vote whether to recommend that the FDA grant AA to the Pozi NDA based on a benefit-risk analysis, FDA officials repeated what they had been privately telling Defendants Lebel and/or Riga since before the start of the Class Period:

we did not come to any formal agreement about the 8-mg BID dose. It's very limited data, and we told [Spectrum] that it would be at their own risk to move forward with this incongruent dose [(8 mg BID)] . . . I think a lot of this speaks to [Spectrum] kind of rushing this development program and trying to take catchup steps, whereas the steps should have been taken slowly, and methodically, and appropriately early in development. . . . [Defendants] have missed several opportunities and several steps along the way to optimize this dose . . . This is a fatal [] flaw in this development program

Proceeding with a drug development program when you don't have a well-founded dose is literally building a house on quicksand here, and this is one of the problems

[PINNACLE] has not enrolled any patients as of this month, and is not slated to read out until 2026 at the earliest. Patients could be exposed to a highly toxic drug with unverified clinical benefit for at least four years.

(Emphasis added).

17. Indeed, Defendants' false representations misled analysts that covered Spectrum. For example, a May 16, 2022 report published by JMP Securities LLC ("JMP") stated "Spectrum noted that it has started enrolling patients" in the PINNACLE Study "which needs to be substantially enrolled by" November 2022; a May 13, 2022 report published by H.C. Wainwright & Co., LLC ("H.C. Wainwright") stated "the PINNACLE study utilizing 8 mg BID bodes well for the potential approval"; and in a May 13, 2022 research report, Jefferies LLC ("Jefferies") reported that Spectrum "announced alignment w/FDA on confirmatory ph.III [] design . . . the confirmatory

² ODAC is an independent panel of experts that reviews and evaluates data concerning the efficacy and safety of investigational products for use in the treatment of cancer. ODAC makes nonbinding recommendations to the FDA regarding product approval.

study is an important moving part, b/c FDA has iterated the importance of having the confirmatory trial 'substantially enrolled' by the time of approval", when, in fact, Spectrum was not aligned with the FDA on the design of the PINNACLE Study and at that point no patients had been enrolled in the PINNACLE Study.

- 18. Defendants were motivated to take a risky gamble and prematurely rush the Pozi NDA and the PINNACLE Study without the dose optimization data required by the FDA and mislead investors because Spectrum was in a precarious financial condition and needed to raise cash. Spectrum was on track to run out of cash by the end of 2022. As of December 31, 2021, Spectrum reported cash, cash equivalents and marketable securities of approximately \$100 million and had reported spending at least \$25 million per quarter (with no revenue from commercial sales).
- 19. During the period April 2022 through May 12, 2022, Defendants Riga and Brennan caused Defendant Spectrum to sell 1.4 million shares of Spectrum common stock for proceeds of \$1.4 million under an at-the-market ("ATM") sales agreement with Cantor Fitzgerald & Co. ("Cantor Fitzgerald"), H.C. Wainwright and B. Riley FBR, Inc. ("B. Riley"), dated April 5, 2019, (the "April 2019 ATM Agreement.").
- 20. On May 18, 2022, Defendants Riga and/or Lebel met with the FDA, and FDA officials again expressed concerns regarding the safety profile of pozi, particularly at the 16 mg QD dose, given the high rate of dose reductions and dose interruptions. FDA stated that additional clinical data at a dosage of 8 mg BID and other dosages was necessary to assess the risk-benefit profile. FDA expressed concern to Defendants Riga and/or Lebel about the delayed enrollment in the PINNACLE Study and communicated that based on the ongoing review, uncertainties remained regarding whether the proposed dosage for AA of 16 mg QD is optimized from both the

efficacy and safety perspectives. Unknown to investors, as of May 18, 2022, no patients had enrolled in the PINNACLE Study.

- 21. During the period May 13 through June 30, 2022, Defendants Riga and Brennan caused Defendant Spectrum to sell 4,219,827 shares of Spectrum common stock for proceeds of \$3,547,000 under the April 2019 ATM Agreement.
- 22. On July 28, 2022, Defendants Riga and/or Lebel met with the FDA to discuss the adequacy of dosage optimization to support both the proposed dose of 16 mg QD for AA and the 8 mg BID dose for PINNACLE Study. The FDA reiterated its concerns regarding the safety and efficacy of pozi, that Defendants had inadequate data on dosing, and that the Company delayed enrollment in the PINNACLE study. Specifically, the FDA stated that the proposed dosage of 16 mg QD for AA did not appear adequately justified and additional data was required to compare the benefit-risk profiles of the 16 mg QD to alternative dosage regimens. Additionally, the FDA asked Defendants Riga and/or Lebel for an update on the PINNACLE Study. Unknown to investors, as of July 28, 2022, no patients had been enrolled in the PINNACLE Study.
- 23. During the period July 2022 through August 12, 2022, Defendants Riga and Brennan caused Defendant Spectrum to sell 5.1 million shares of Spectrum common stock for proceeds of approximately \$4.5 million under the April 2019 ATM Agreement.
- 24. On August 11, 2022, Defendants Riga, Lebel and Brennan caused Spectrum to issue a press release concerning the Company's financial results for the quarter ended June 30, 2022 that represented:

A study for poziotinib is in progress to confirm the clinical benefit seen in Cohort 2, as required for an accelerated approval. The trial, Study SPI-POZ-301 (PINNACLE), is designed to enroll 268 patients with previously treated NSCLC harboring HER2 exon 20 mutations. Patients are being randomized 2-to-1 into one of two treatment arms using 8mg of poziotinib orally administered BID

(twice daily) versus 75mg/m2 of docetaxel administered intravenously every three weeks. The primary endpoint is progression free survival.

(Emphasis added).

- 25. Also on August 11, 2022, during a Spectrum conference call with investors, an analyst asked Defendants Riga, Lebel and Brennan "on [the PINNACLE Study], how many sites are active right now? What percentage of your target patients have been enrolled in Phase III? And where do you need to be on enrollment to satisfy FDA's focus on substantial enrollment by [November 24, 2022]?"
- 26. While knowing, or at least recklessly disregarding, that FDA had repeatedly expressed concerns about pozi's efficacy, safety and lack of adequate dosing optimization data, that Spectrum and the FDA did not agree on the design of the PINNACLE Study and that Defendants were pressing forward in the face of being told by the FDA that they were proceeding at their own risk, and that as of August 11, 2022 no patients had enrolled in the PINNACLE Study, Defendant Lebel made the following materially false and misleading statements: "we're very active in opening site[s]. But as I'm sure you know, it takes a long time to open sites. We have some site[s] open. I'm not going to give you numbers today. I'm not going to speak directly to enrollment today. And so we're moving as fast as we can internationally as well as in North America."
- 27. Defendant Lebel's false and misleading representations reaffirmed investors' impression about the status of the PINNACLE Study that differed in a material way from the one that actually existed, in violation of the federal securities laws. Indeed, on August 12, 2022, H.C. Wainwright published a report concerning Spectrum that stated "the PINNACLE study utilizing 8 mg BID bodes well for the potential approval."
 - 28. During the period August 13 through September 30, 2022, Defendant Riga and

Brennan caused Defendant Spectrum to sell 13,794,118 shares of Spectrum common stock for proceeds of \$17,113,000 under the April 2019 ATM Agreement.³

- 29. On September 8, 2022, Defendants Riga and/or Lebel met with the FDA. The FDA reiterated its concerns regarding the safety and efficacy of pozi, that Defendants had inadequate data on dosing, and that the Company had delayed the PINNACLE study. Specifically, the FDA indicated that based on the ongoing review, uncertainties remained regarding whether the proposed dosage of 16 mg QD was optimized from both the efficacy and safety perspectives. The FDA again stated that additional clinical data was needed to compare the benefit-risk profiles of the 16 mg QD dosage to alternative dosage regimens. Unknown to investors, as of September 8, 2022, no patients had been enrolled in the PINNACLE Study.
- 30. Starting on September 20, 2022, before the market opened, investors began to learn the truth when the FDA released the FDA Briefing Document, Oncologic Drugs Advisory Committee Meeting (the "FDA Briefing Document") in anticipation of its September 22, 2022 meeting with Defendants Spectrum and Lebel to review the Pozi NDA.
- 31. Investors were surprised when, despite Riga and Lebel's representations that Spectrum had learned to optimize the dosage for pozi, and that Spectrum was enrolling patients in the PINNACLE Study, the FDA Briefing Document disclosed that before the filing of the Pozi NDA (November 2021), the FDA had repeatedly told Defendants Spectrum, Riga and/or Lebel that they had inadequate data on dosing, that additional data and studies were needed to determine whether Defendants' dose selection for pozi was optimized, that the FDA had concerns regarding the efficacy and safety study data results from Cohort 2 and the delayed enrollment in the

³ Because Spectrum's SEC filings do not provide the specific dates or price per share of the transactions sold under the April 2019 ATM Agreement, some or all of these shares may have been sold after the Class Period. This is information that is within Defendants' possession, custody and control and would be a subject of discovery.

PINNACLE study, and that as of September 20, 2022 no patients had enrolled in the PINNACLE Study.

- 32. As a result of this news disclosed to investors for the first time in the FDA Briefing Document, shares of Spectrum common stock declined from a closing price of \$1.06 per share on September 19, 2022, to a close at \$0.66 per share on September 20, 2022, a decline of \$0.40 per share, or over 37% on heavier than usual volume.
- 33. On September 20, 2022, Cantor Fitzgerald, issued a report titled "FDA Briefing Docs Negative for Poziotinib Approval" and discussed the FDA concerns revealed by the FDA Briefing Document. Also on September 20, 2022, H.C. Wainwright released a report entitled "Upcoming ODAC meeting for pozi could be more argumentative than we initially thought . . . "[i]mportantly, the confirmatory study of poziotinib 8mg BID [PINNACLE] has not yet started . . . [t]he focus on dosing optimization in the briefing documents give us some pause."
- 34. On September 22, 2022, before the opening of the market, trading in Spectrum common stock on Nasdaq was halted at \$0.63 per share pending the outcome of the ODAC meeting.
- 35. On September 22, 2022, the FDA's ODAC (Oncologic Drugs Advisory Committee) conducted its meeting concerning pozi in which Defendant Lebel participated on behalf of the Company. The ODAC meeting involved presentations by the FDA review team, the Company, and others, and a question and answer period. Two FDA officials stated that the FDA and the Company did not reach an agreement on the design of the PINNACLE Study to treat patients at the 8 mg BID dose and that the FDA warned the "sponsor [Spectrum] that it would be at their own risk to move forward with this incongruent dose." Defendant Lebel admitted that no patients had enrolled in the PINNACLE Study. At the end of the meeting, ODAC members voted

9-4 that pozi's purported benefits did not outweigh its risks, which was a recommendation that the FDA not approve the Pozi NDA.

- 36. As a result of this news, when trading in Spectrum common stock resumed on September 23, 2022, shares of Spectrum common stock further declined from a closing price of \$0.63 per share on September 21, 2022 before trading was halted, to a close at \$0.43 per share on September 23, 2022, a decline of \$0.20 per share, or over 31% on heavier than usual volume.
- 37. On September 23, 2022, H.C. Wainwright published a report that stated "[w]e believe the ODAC vote is negative for potential approval of poziotinib. We note that the FDA does not have to follow the recommendations of the ODAC; however, the FDA's views in the briefing documents and during the meeting do not bode well for approval, in our opinion." Also on September 23, 2022, Jefferies released a report titled "Based on Negative Pozi Adcom, We Anticipate CRL; Next Steps for Pozi Unclear". B. Riley issued a report that stated ODAC's negative vote followed "an excruciating FDA review that had been previously evident in the company's correspondence with the agency since NDA acceptance" in February 2022.
- 38. On November 25, 2022, Spectrum issued a press release disclosing receipt of a complete response letter (CRL) from the FDA regarding the Pozi NDA and that the Company would "deprioritize" development of pozi:

Spectrum... has received a [CRL] from the [FDA] regarding [the Pozi NDA]. The FDA issued a CRL indicating the poziotinib application cannot be approved in its present form. Based on the CRL, the Company would have to generate additional data including a randomized controlled study prior to approval.

"While we are not surprised by the CRL given the ODAC recommendation in September, we are disappointed. After multiple interactions with the FDA since ODAC, and following careful consideration, we have made the strategic decision to immediately de-prioritize the poziotinib program," said [Defendant] Riga . . . The Company will de-prioritize poziotinib program activities, effective immediately, and is in the process of reducing its R&D workforce by approximately 75%.

(Emphasis added).

- 39. On January 4, 2023, given his prominent role in interacting with the FDA on behalf of the Company and his blatant misrepresentations to investors, unsurprisingly, Spectrum filed a report on Form 8-K with the SEC and issued a press release stating that Defendant Lebel "resigned from employment" as the Company's EVP and CMO, effective December 31, 2022.
- 40. In the 90-trading days after the end of the Class Period, Spectrum shares did not recover, trading at an average price of \$0.43 per share.
- 41. As alleged herein, during the Class Period, Defendants violated the federal securities laws by making false or misleading representations or by failing to disclose material facts they had a duty to disclose while selling millions of shares of Spectrum common stock at artificially inflated prices. Defendants should be held accountable for these violations of the federal securities laws.

II. JURISDICTION AND VENUE

- 42. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5. Jurisdiction for this Court is conferred over the subject matter of the Action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.
- 43. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. § 1391(b). The acts and transactions giving rise to the violations of law complained of occurred in part in this District, including the dissemination of false and misleading statements into and from within this District. In addition, Spectrum's common stock trades on the NASDAQ in this District under the symbol SPPI. On or around June 16, 2022, Defendants Riga and Lebel participated in the JMP Securities Life Sciences Conference in this District, and on or around June 9, 2022 Defendants Lebel and Riga participated in the Jefferies

Healthcare Conference in this District. Members of the proposed Class, including several institutional investors, have offices in this District. Under the April 2019 ATM Agreement, which is governed by New York law, each time the Company sold shares during the Class Period, the sales were effected by and through either Cantor Fitzgerald, H.C. Wainwright & Co., or B. Riley through their respective employees or agents at offices in this District.

44. In connection with the acts and conduct alleged in the Action, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails and interstate wire and telephone communications.

III. PARTIES

- 45. Plaintiff purchased Spectrum common stock during the Class Period as described in the Certification attached hereto, and suffered damages as a result of the violations of the federal securities laws alleged herein.
- 46. Defendant Spectrum is a biopharmaceutical company that is incorporated in Delaware, and has its headquarters in Boston, Massachusetts. Spectrum's common stock is traded under the symbol SPPI on the NASDAQ in this District. According to Spectrum's annual report for the year ended December 31, 2021 filed with the SEC on March 18, 2022 on Form 10-K ("2021 10-K"), there were 177,151,513 shares of the Company's common stock outstanding as of March 10, 2022. According to the 2021 10-K, the Company's primary strategy purported to be acquiring, developing, and commercializing novel and targeted oncology therapies, and the Company had two drugs in late-stage development, pozi, and eflapegrastim (branded Rolontis), a drug for the treatment of chemotherapy-induced neutropenia (low white blood cells). During the Class Period, Spectrum reported no revenue from sales of commercial products.
- 47. Defendant Riga was appointed the Company's President and CEO and a member of the Company's board of directors effective December 31, 2021, and served in those roles

throughout the Class Period. During the period March 18, 2022 through May 25, 2022 (which was the effective date of Defendant Brennan's appointment), Defendant Riga served as Interim Principal Financial Officer of the Company. At the time he was appointed CEO, he was serving as the Company's Chief Commercial Officer ("CCO") and Chief Operating Officer ("COO"). Defendant Riga joined the Company in July 2013 as Vice President of Corporate Accounts and was named CCO in August 2014 and COO in December 2017. He made materially false and misleading statements and omitted material facts he had a duty to disclose in Spectrum's SEC filings, press releases or on public conference calls with analysts and investors during the Class Period.

- 48. Defendant Lebel was appointed CMO on November 18, 2018 and was the Company's EVP and CMO throughout the Class Period. Effective December 31, 2022, he resigned from his positions with the Company. He made materially false and misleading statements and omitted material facts he had a duty to disclose in Spectrum's SEC filings, press releases or on public conference calls with analysts and investors during the Class Period. During the Class Period, Defendant Lebel sold a total of 15,335 shares of Spectrum common stock for proceeds of over \$14,000.
- 49. Defendant Brennan was appointed as the Company's CFO and EVP on May 11, 2022, effective May 25, 2022. Prior to being appointed CFO, Defendant Brennan served on Spectrum's Board of Directors and as Chairperson of the Audit Committee since December 2020. She made materially false and misleading statements and omitted material facts she had a duty to disclose in Spectrum's SEC filings during the Class Period. During the Class Period, Defendant Brennan sold 3,569 shares of Spectrum common stock for proceeds of \$2,819.51.

- 50. Defendants Riga, Lebel and Brennan (the "Individual Defendants"), as senior executives of Spectrum, acted within the scope of their respective authority and as agents of Spectrum during the Class Period.
- 51. The Individual Defendants, because of their respective positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases, and representations and presentations to securities analysts, money and portfolio managers, and institutional and individual investors, *i.e.* the market. They were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected.

IV. FACTUAL BACKGROUND AND DEFENDANTS' FRAUDULENT CONDUCT

- A. The FDA Regulatory Process for Regular Drug Approval
- 52. Before any new drug can be marketed and sold commercially in the U.S., the FDA requires that the drug undergo pre-clinical (animal) trials, and clinical trials involving three phases of human testing, with each phase involving increasingly larger patient pools.
- 53. During pre-clinical testing stage, laboratory and animal studies are conducted to show biological activity of a drug against the targeted disease. The compound is evaluated for safety. After certain pre-clinical studies are completed, an Investigational New Drug Application ("IND") is submitted to the FDA to request the ability to begin human testing of the drug. An IND becomes effective thirty days after the FDA receives the application (unless the FDA notifies the sponsor of a clinical hold), or upon prior notification by the FDA.
- 54. *Phase 1 Clinical Trials:* These trials typically involve small numbers of healthy volunteers or patients and usually define a drug candidate's safety profile, including the safe dosage range.

- 55. Phase 2 Clinical Trials: In Phase 2 clinical trials, controlled studies of human patients with the targeted disease are conducted to assess the drug's effectiveness. These studies are designed primarily to determine the appropriate dose levels, dose schedules and route(s) of administration, and to evaluate the effectiveness of the drug on humans, as well as to determine if there are any side effects on humans to expand the safety profile following Phase 1. These clinical trials, and Phase 3 trials discussed below, are designed to evaluate the product's overall benefit-risk profile, and to provide information for physician labeling.
- 56. Phase 3 Clinical Trials: This Phase usually involves a larger number of patients with the targeted disease. Investigators (typically physicians) monitor the patients to determine the drug candidate's efficacy and to observe and report any adverse reactions that may result from long-term use of the drug on a large, more widespread, patient population. During the Phase 3 clinical trials, typically the drug candidate is compared to either a placebo or a standard treatment for the target disease in a randomized trial where some patients are treated with the drug candidate, and some are treated with a placebo or a standard treatment.
- 57. *New Drug Application:* After completion of all three clinical trial Phases, if the data indicate that the drug is safe and effective, an NDA is filed with the FDA requesting FDA approval to market the new drug as a treatment for the target disease.

B. The FDA's Accelerated Approval (AA) Pathway

- 58. The AA pathway aims to speed the regular drug approval process outlined above on the basis of Phase 1 or 2 study data results relating to a surrogate endpoint deemed reasonably likely to predict clinical benefit or an intermediate clinical end point other than irreversible illness or death. AA may be sought for drugs that treat a serious condition and provide a meaningful advantage over available therapies.
 - 59. According to the FDA's Guidance for Industry, Expedited Programs for Serious

Conditions – Drugs and Biologics (May 2014), a drug sponsor should ordinarily discuss the possibility of AA with the review division during development, supporting, for example, the use of the planned endpoint as a basis for approval and discussing confirmatory trials, which should usually be already underway at the time of AA.

- 60. For drugs granted AA, postmarketing confirmatory trials (also called postmarketing requirements, or PMR) have been required to verify clinical benefit, and these additional trials must be completed with due diligence. The FDA has interpreted the due diligence requirement to mean that the postmarketing trial intended to verify the clinical benefit must be conducted promptly to facilitate determination, as soon as possible, of whether clinical benefit has been verified or not verified.
- 61. A May 6, 2021 article published in the *New England Journal of Medicine* ("NEJM") titled "'Dangling' Accelerated Approval in Oncology" that was authored by two FDA officials, Dr. Julia A. Beaver⁴ and Dr. Richard Pazdur⁵ stated that "[t]o improve their timely completion, confirmatory trials should be ongoing, if not fully enrolled, at the time of accelerated approval." Both Dr. Beaver and Dr. Pazdur were involved in the review of the Pozi NDA and the ODAC meeting at the end of the Class Period, as alleged below.
- 62. If a drug is granted AA and marketed for use in patients, a delay in the timely completion of a confirmatory trial represents the greatest risk to patients. The FDA desires that drug sponsors provide sufficient evidence of effectiveness and adequate of assurance of safety, while expediting access to drugs and minimizing the time between AA and demonstration of

⁴ Julia A. Beaver M.D. ("Dr. Beaver") was Chief of Medical Oncology, of the FDA's Oncology Center of Excellence ("OCE"), Deputy Director (Acting) of the Office of Oncologic Diseases ("OOD") and the FDA's Center for Drug Evaluation and Research ("CDER").

⁵ Richard Pazdur, M.D. ("Dr. Pazdur") was the Director of OCE, Director (Acting) of ODD, Office of New Drugs ("OND") and CDER.

clinical benefit or lack of clinical benefit.

C. Spectrum Studies Pozi on Previously Treated NSCLC Patients with HER2 Exon 20 Mutations

- 63. NSCLC accounts for approximately 85% of all lung cancers. The main difference between NSCLC and small cell lung cancer ("SCLC") is the way the cells appear under a microscope. SCLC cells appears as flat and smaller than cancer cells in NSCLC. SCLC typically grows faster than NSCLC and often spreads to the lymph nodes.
- 64. Enzymes are proteins that act as biological catalysts by accelerating chemical reactions. Receptor tyrosine kinases ("RTKs") are a type of enzyme that regulate cellular functions, including cell growth and metabolism. HER2 is a type of RTK and is present on cell membranes of cells in the lungs.
- 65. Mutations or insertions in HER2 can lead to NSCLC. According to Spectrum, up to 86% of the HER2 tumor-causing mutations are exon 20 insertions, which represents approximately 3,000 newly diagnosed patients per year in the U.S.
- 66. Pozi is purportedly a novel, oral inhibitor of tyrosine kinases ("TKI"), including HER2 exon 20 insertion mutations. Pozi purportedly has a unique structure that inhibits certain cellular activity linked to cancer. Pozi is administered orally. TKIs like pozi are targeted treatments, unlike chemotherapy and other cancer treatments toxic to cells.
- 67. On or around July 28, 2017, Spectrum submitted an IND for pozi to the FDA. Spectrum initiated a clinical development program for pozi called ZENITH20 (Study SPI-POZ-202) to study pozi for different indications or exploratory purposes and ultimately comprised 7 cohorts.
- 68. Cohort 2 was a stand-alone, independent Phase 2 study concerning the efficacy and safety of pozi at a dose of 16 mg QD in previously treated (second-line) NSCLC patients with

HER2 exon 20 insertion mutations. The primary endpoint of Cohort 2 was objective response rate, or ORR (which measured complete or partial decrease in the size of tumor or cancer).

D. The FDA Raises Concerns that Spectrum's Dose Selection Was Not Optimized

- 69. Spectrum's dose selection of 16 mg QD was based on a preliminary Phase 1 study conducted in South Korea involving approximately 20 patients (the "Phase 1 Study"). The Phase 1 Study dosed three patients at 12 mg QD, seven to eight patients at 16 mg QD, six patients at 18 mg QD, and three patients at 24 mg QD.
- 70. On or around July 28, 2017, unknown to investors, the FDA communicated concerns to Spectrum that the 16 mg QD dose was not optimized. Dose optimization is essential to ensure that patients receive therapies which maximize efficacy while minimizing toxicity. Because the Phase 1 Study involved few patients, the FDA determined that there were very limited safety and preliminary activity data available. The FDA further determined that the insufficient study data results from the Phase 1 Study were not adequate to differentiate the risk-benefit profile of the clinically active dose range (12mg to 16 mg per day) in the proposed patient population.
- 71. The FDA made clear to Spectrum that the Phase 1 Study did not support dose optimization for pozi. The FDA reiterated concerns to Spectrum during the pozi development program and throughout the Class Period that Spectrum did not have adequate study data results that confirmed optimal dose selection.

E. Defendants Spectrum and Lebel Study Pozi in BID (twice per day) Dosing

- 72. On February 27, 2020, Defendants Spectrum and Lebel disclosed that Cohort 2 was fully enrolled and that top-line results were expected by mid-2020. All Cohort 2 patients were treated with 16 mg QD.
 - 73. On May 7, 2020, Defendants Spectrum and Lebel disclosed that Spectrum would

study additional dosing schedules beyond the 16mg QD due to high rates of dose interruptions. In an exploratory study (Cohort 5), patients would receive 10 mg QD, or 6 or 8 mg BID.

F. Defendants Spectrum and Lebel Release Cohort 2 Study Data Results

- 74. On July 27, 2020, Defendants Spectrum and Lebel stated that Cohort 2 met its prespecified endpoint. The ORR was 27.8% and the lower bound of the 95% confidence interval exceeded the pre-specified criterion of 17%. Defendants Spectrum and Lebel also stated the results of secondary endpoints: the median duration of response ("DOR") was 5.1 months, the disease control rate ("DCR") was 70%, and median progression free survival was 5.5 months.
- 75. On November 9, 2020, Defendant Lebel met with the FDA in a telephonic Type B Pre-NDA meeting to discuss the adequacy of the safety and efficacy results from Cohort 2 during which Defendant Lebel presented top-line data from Cohort 2. The FDA determined that Spectrum could submit an NDA for pozi under the FDA's AA pathway for substantive review, however, unknown to investors, the FDA reiterated to Defendant Lebel the FDA's ongoing concerns regarding the efficacy and safety data, inadequate dose selection data and the FDA requested additional data on dose optimization be provided in the NDA.

G. The FDA Reiterates Material Concerns that Spectrum Did Not Have Adequate Data to Optimize the 16 mg QD Dose

- 76. On July 16, 2021, Defendant Lebel participated in a Type C guidance meeting with the FDA to discuss Spectrum's planned confirmatory trial and whether the BID dosing from the ongoing exploratory study (Cohort 5) could be submitted with the Pozi NDA.
- 77. The FDA reiterated concerns about the dosing data from Cohort 2 and that it was not known based on Spectrum's study data if alternative dosages provided similar effectiveness compared to the 16 mg QD dose. While the initial dosage in Cohort 2 was 16 mg QD, due to dose interruptions from adverse events (89% of patients), most patients (74%) received dosages of 12

mg daily or less. FDA agreed with the inclusion of data from the ongoing exploratory study (Cohort 5) in the Pozi NDA and recommended that Spectrum pool all study data from completed trials and perform analyses of the data to justify that 8 mg BID was the optimum biologic dosage and schedule. In addition to data from Cohort 2 and the ongoing exploratory study (Cohort 5), Spectrum had data on NSCLC patients treated with 16 mg QD or 8 mg BID from an investigator-sponsored study and from other ZENITH20 cohorts.

- 78. On October 1, 2021, Spectrum submitted the first portion of the rolling submission of the Pozi NDA under the AA pathway.
- 79. During a Spectrum earnings conference call with investors on November 10, 2021 in which Defendant Lebel participated, an analyst asked Defendant Lebel "what confirmatory study are you committing to in terms of design? Because obviously you need to do that as part of the [] approval? In response, Defendant Lebel stated:

... we're in discussion with the [FDA] regarding this, and we clearly have developed a PMR [(post-marketing requirement, i.e. PINNACLE)]. And when you file the NDA, you have to have a PMR essentially underway and so we absolutely intend to do that. But obviously, want to make sure we're in complete agreement ... as to the nature of the PMR.

So I'm not going to go any further on that, but it's probably a randomized controlled study . . . And we'll need to define that with the [FDA] and probably quite soon, you will be able to see what we're doing.

(Emphasis added).

80. On November 24, 2021, Spectrum submitted the final components of the Pozi NDA to the FDA. Defendants Spectrum and Lebel sought AA approval of the 16 mg pozi QD dose based on the Cohort 2 study data results, despite the fact that, since 2017, the FDA reiterated concerns that Spectrum did not have adequate data to justify the 16 mg QD dose. The Pozi NDA also included the additional dosing data from the ongoing exploratory study (Cohort 5) that Defendant Lebel discussed at the July 16, 2021 meeting with FDA officials as supportive data to

justify dosing patients at lower doses than 16 mg QD.

81. The ongoing exploratory study (Cohort 5) was treating patients with lower doses of pozi, including 6 and 8 mg BID, in very limited numbers and was studying a mix of NSCLC patients, only some of whom were like the patients treated in Cohort 2 (i.e., second-line NSCLC with HER2 exon 20 mutations).

H. Defendants Spectrum and Lebel Meet with the FDA to Discuss the PINNACLE Study

- 82. In November 2021, the FDA began its formal review of the Pozi NDA and, as one FDA official disclosed after the Class Period, the concerns that the FDA had previously expressed to Defendants Spectrum and Lebel were "confirmed and magnified".
- 83. Days later, on December 13, 2021, Defendant Lebel participated in a Type B Prephase 3 meeting with the FDA to discuss the proposed design of the PINNACLE Study. For the PINNACLE Study, Defendant Lebel proposed a dosage regimen of 16 mg QD for 2 weeks followed by 8 mg BID or 6 mg BID. The FDA raised concerns that the data submitted with the Pozi NDA was inadequate and that it was not known if alternative dosages provided similar effectiveness compared to the 16 mg QD dosage, and stated that additional dosing data were needed to determine whether the pozi dose was optimized for further evaluation in the PINNACLE Study.
- 84. Specifically, the FDA indicated to Defendant Lebel that Spectrum should evaluate the 6 mg BID dose in one or more confirmatory trials, potentially conducted as a run-in phase, and that the 8 mg BID dose as the starting dose was preferable to 16 mg QD that Spectrum proposed. A run-in phase study would occur before the confirmatory trial, adding both time and expense to the pozi development program. Spectrum and FDA did not reach an agreement on the design of the PINNACLE Study due to the inadequate optimization study data and incongruent dosing

regimens proposed by Defendant Lebel.

- 85. On February 7, 2022, Defendants Riga and/or Lebel participated in a Type B End of Phase 2 meeting with the FDA to discuss Spectrum's design for PINNACLE to treat patients with an 8 mg BID dosage. The FDA requested additional efficacy data from patients enrolled in the ongoing exploratory study (Cohort 5) to further analyze the antitumor activity of pozi 8 mg BID. The FDA expressed concern about the delay in the initiation of the PINNACLE Study and emphasized the need to begin enrollment as soon as possible. Further, the FDA reiterated its concerns regarding top line efficacy results, lack of dosage optimization, delayed confirmatory trial status, and the safety profile of pozi. The FDA and Spectrum did not reach an agreement on the design of the PINNACLE Study.
- 86. On February 11, 2022, Defendants Riga and Lebel caused Spectrum to issue a press release titled "Spectrum Pharmaceuticals Announces Acceptance of New Drug Application Filing for Poziotinib" that stated the following:

The NDA acceptance is based on the positive Phase 2 study results in patients with previously treated locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring HER2 exon 20 insertion mutations. There is currently no treatment specifically approved by the FDA for this indication. The product has received Fast Track designation and the agency has set a Prescription Drug User Fee Act (PDUFA) date of November 24, 2022. The FDA reiterated the importance of having the confirmatory trial substantially enrolled at the time of approval and requested additional information around dosing. . . .

I. Defendants' Fraudulent Conduct

87. The Class Period begins on March 17, 2022, when, during Spectrum's conference call with investors and analysts to discuss the Company's fourth quarter 2021 and full year 2021 financial results, Defendant Riga, while knowing, or at least recklessly disregarding that the FDA repeatedly told Defendants Lebel and/or Riga that Spectrum's dose optimization data was inadequate and that additional data and studies were needed to determine whether Defendants'

dose selection for pozi was optimized for further study in the PINNACLE Study utilizing 8 mg BID, falsely represented that "we have learned to optimize some of the tolerability and abate some of the AEs here with the BID dosage."

- 88. During the period April 2022 through May 12, 2022, Defendants Riga and Brennan caused Defendant Spectrum to sell 1.4 million shares of Spectrum common stock for proceeds of \$1.4 million under the April 2019 ATM Agreement. On April 4, 2022, Defendant Lebel sold 1,205 shares of Spectrum common stock at a price of \$1.35 per share, for proceeds of approximately \$1,626.75. On April 5, 2022, Defendant Lebel sold 1,367 shares of Spectrum common stock at a price of \$1.41 per share, for proceeds of approximately \$1,927.47.
- 89. On May 12, 2022, Defendants Riga and Lebel participated in a Spectrum conference call with investors during which Defendant Riga and Lebel disclosed the design of the PINNACLE Study to treat patients with pozi at the 8 mg BID dose, and falsely represented that the PINNACLE Study was enrolling patients ("patients are being randomized") and that Defendants and the FDA were "obviously aligned" on the PINNACLE Study design to treat patients at the 8 mg BID dose.
- 90. In truth, unknown to investors, as of May 12, 2022 no patients had enrolled in the PINNACLE Study and the FDA did not agree with Spectrum's proposed design for the PINNACLE Study to treat patients with 8 mg of pozi BID due to Spectrum's inadequate dose optimization data. Moreover, far from being "aligned", the FDA told Defendants Riga and/or Lebel that the FDA did not agree on the design of the PINNACLE Study to treat patients with 8 mg BID and warned Defendants, in light of the FDA's concerns about the dosing, efficacy and safety data, that proceeding with the 8 mg BID dose in the PINNACLE Study was at their own risk.

- 91. Defendants Riga and Lebel's representations were materially false and misleading because they created the false impression that the PINNACLE Study was enrolling patients, that PINNACLE was on track to be substantially enrolled by November 24, 2022 (the PDUFA date), and that Defendants and the FDA were aligned concerning the design of the PINNACLE Study to treat patients at the 8 mg BID dose, none of which were true.
- 92. Indeed, Defendant Riga and Lebel's misrepresentations misled analysts who covered Spectrum stock. In a May 13, 2022 research report, Jefferies reported that Spectrum "announced alignment w/FDA on confirmatory ph.III [] design . . . the confirmatory study is an important moving part, b/c FDA has iterated the importance of having the confirmatory trial 'substantially enrolled' by the time of approval."
- 93. Also on May 13, 2022, H.C. Wainwright & Co. published a report that stated "the PINNACLE study utilizing 8 mg BID bodes well for the potential approval."
- 94. On May 16, 2022, JMP published a report that stated "Spectrum noted that it has started enrolling patients" in the PINNACLE Study.
- 95. During the period May 13 through June 30, 2022, Defendants Riga and Brennan caused Defendant Spectrum to sell 4,219,827 shares of Spectrum common stock for proceeds of \$3,547,000.
- 96. On May 18, 2022, Defendants Riga and/or Lebel participated in a Midcycle Communication meeting with the FDA in which FDA again expressed concerns regarding the safety profile of pozi, particularly at the 16 mg QD dose, given the high rate of dose reductions and dose interruptions. Again, the FDA told Defendants Riga and/or Lebel that additional clinical data at a dosage of 8 mg BID and other dosages was necessary to assess pozi's risk-benefit profile. FDA expressed concern to Defendants Riga and/or Lebel about the delayed enrollment in the

PINNACLE Study and communicated that based on the ongoing review, uncertainties remained regarding whether the proposed dosage of 16 mg QD is optimized from both the efficacy and safety perspectives.

- Defendant Spectrum to sell 5.1 million shares of Spectrum common stock for proceeds of approximately \$4.5 million under the April 2019 ATM Agreement. On June 21, 2022, Defendant Brennan sold 3,569 shares of Spectrum common stock at a price of \$0.79 per share, for proceeds of approximately \$2,819.51. On June 22, 2022, Defendant Lebel sold 6,096 shares of Spectrum common stock at a price of \$0.81 per share, for proceeds of approximately \$4,937.76. On June 23, 2022, Defendant Lebel sold 6,667 shares of Spectrum common stock at a price of \$0.84 per share, for proceeds of approximately \$4,937.76. On June 23, 2022, Defendant Lebel sold 6,667 shares of Spectrum common stock at a price of \$\$0.84 per share, for proceeds of approximately \$5,600.28.
- 98. On July 28, 2022, Defendants Riga and/or Lebel participated in a Type B Guidance meeting with the FDA to discuss the adequacy of dosage optimization data to support both the proposed dose of 16 mg QD for the Pozi NDA and the 8 mg BID dose for the PINNACLE Study. The FDA again stated that the proposed dosage of 16 mg QD does not appear adequately justified and that additional clinical data from the ongoing exploratory study (Cohort 5) and the PINNACLE Study (which as of July 28, 2022 had not enrolled any patients) were needed to compare the benefit-risk profiles of the 16 mg QD to alternative dosage regimens. Additionally, FDA asked for an update on the planned confirmatory trial. As of July 28, 2022, no patients had been enrolled in the PINNACLE Study.
- 99. On August 11, 2022, Defendants disclosed Spectrum's financial results for the quarter ended June 30, 2022 and held a conference call with investors. Defendants Riga and Lebel again falsely represented that that patients were enrolling in the PINNACLE Study. During the

conference call, an analyst asked Defendants Riga, Lebel and Brennan "on the confirmatory Phase III, how many sites are active right now? What percentage of your target patients have been enrolled in Phase III? And where do you need to be on enrollment to satisfy FDA's focus on substantial enrollment by PDUFA date?"

- 100. While knowing, or at least recklessly disregarding, that FDA had repeatedly expressed concerns about pozi's efficacy, safety and lack of adequate dosing optimization data, that Spectrum and the FDA did not agree on the design of the PINNACLE Study and that Defendants were pressing forward in the face of being told by the FDA that they were proceeding at their own risk, and that as of August 11, 2022 no patients had enrolled in the PINNACLE Study, Defendant Lebel made the following materially false and misleading statements: "we're very active in opening site[s]. But as I'm sure you know, it takes a long time to open sites. We have some site[s] open. I'm not going to give you numbers today. I'm not going to speak directly to enrollment today. And so we're moving as fast as we can internationally as well as in North America."
- 101. Defendant Lebel's false representations misled investors concerning the true status of enrollment in the PINNACLE Study and that the FDA and Spectrum did not agree on the design to treat patients with 8 mg BID in the PINNACLE Study. Indeed, on August 12, 2022, H.C. Wainwright published a report concerning Spectrum that stated we "believe the PINNACLE study utilizing 8 mg BID bodes well for the potential approval."
- 102. Also during the August 11, 2022 conference call, Defendant Riga indicated to investors that he was aware of the FDA's guidance on AA. In response to an analyst's question about the FDA's view on the AA pathway, Defendant Riga stated "we're aware of the kind of macro environment of FDA comments on accelerated approvals."

- 103. During the period August 13 through September 30, 2022, Defendants Riga and Brennan caused Defendant Spectrum to sell 13,794,118 shares of Spectrum common stock for proceeds of \$17,113,000 under the April 2019 ATM Agreement.
- 104. On September 8, 2022, Defendants Riga and/or Lebel participated in a Late Cycle Communication meeting with the FDA in which FDA indicated that based on its ongoing review, uncertainties remain regarding whether the proposed dosage of 16 mg QD is optimized from both the efficacy and safety perspectives. The FDA stated that additional clinical data from Cohort 5 (which was still ongoing) and the PINNACLE Study (which as of September 8, 2022 had not enrolled any patients) were needed to compare the benefit-risk profiles of the 16 mg QD dosage to alternative dosage regimens. As of September 8, 2022 no patients had been enrolled in the PINNACLE Study.

V. THE TRUTH BEGINS TO EMERGE

- 105. On September 20, 2022, before the market opened, the FDA released the FDA Briefing Document ahead of its scheduled September 22, 2022 ODAC meeting regarding the pozi development program and to vote whether to recommend AA to the FDA based on a benefit-risk analysis. In sharp contrast to Defendants Riga and Lebel's representations that the FDA and Defendants were aligned on the design of the PINNACLE Study and that patients had been enrolling, and that Spectrum had learned to optimize the pozi dose, the FDA Briefing Document revealed that before and during the Class Period, the FDA reiterated material, negative concerns about the efficacy and safety data supporting the Pozi NDA, that the FDA informed Defendants Riga and/or Lebel that Spectrum's dosing data was inadequate and that additional data and studies were required to optimize the dose, and revealed that the PINNACLE Study had not enrolled a single patient and initial results were not anticipated for 4-5 years.
 - 106. As a result of these disclosures, the price of Spectrum's common stock declined

from a closing price on September 19, 2022 of \$1.06 per share, to close at \$0.66 per share on September 20, 2022, a decrease of \$0.40 per share or over 37%, on massive trading volume of over 21.85 million shares.

On September 22, 2022, trading in Spectrum stock was halted in advance of the 107. ODAC meeting.

108. Members of the FDA review team who participated in the ODAC meeting included Dr. Pazdur and Dr. Beaver, and other FDA officials who reviewed the Pozi NDA and had meetings and communications with Defendants Riga and/or Lebel before and during the Class Period. As alleged above, in May 2021, Dr. Pazdur and Dr. Beaver published an article in the NEJM that stated "[t]o improve their timely completion, confirmatory trials should be ongoing, if not fully enrolled, at the time of accelerated approval."

Nicole Drezner, M.D., stated the following: 109.

As you will hear in the subsequent FDA presentations, the major review issues were discussed with the applicant prior to submission of the NDA [in November 2021] and throughout poziotinib's development.

Beginning in 2017, we informed the applicant that their plans for dose optimization were not adequate to support a registrational program. When [Spectrum] presented [its] top-line data at a pre-NDA meeting in late 2020, we requested that additional data on dose optimization be provided in the NDA but felt that the application was fileable.

Given that one year elapsed between the pre-NDA meeting and submission of the NDA, our concerns were once again expressed in July 2021, and the applicant committed to providing additional data at the time of NDA submission. Our formal review began in November 2021, which has confirmed and magnified our several concerns. . . .

(Emphasis added).

⁶ Dr. Drezner was a Clinical Team Lead, Division of Oncology 2 ("DO2"), OOD (Office of Oncologic Diseases), OND (Office of New Drugs), CDER (Center for Drug Evaluation and Research).

- 110. Dr. Drezner identified the following "major review issues" which "were discussed with the applicant prior to submission of the NDA and throughout poziotinib's development":
 - 1) the efficacy of pozi, as demonstrated by a limited response rate with poor durability, was not improved over approved second-line therapies. If granted accelerated approval, pozi would be the least effective target therapy for lung cancer approved to date;
 - 2) the high rate of toxicity observed with pozi at 16 mg QD and that it was unclear whether alternative doses, namely 8 mg BID, would improve the toxicity profile associated with pozi. Spectrum did not rigorously assess patient-reported symptoms and side effects, and therefore inadequately assessed tolerability of pozi.
 - 3) Defendants failed to adequately explore various dosages throughout the development program, resulting in disparate dosages being investigated (16 mg QD) versus the planned confirmatory trial (8 mg BID) and inadequate optimization of the pozi dosage throughout the development, raising concerns that the 16 mg QD may not represent the optimal regimen; and
 - 4) The delay in confirmation of benefit and that despite ongoing discussions with the FDA about the need for a confirmatory trial beginning as early as 2020, that enrollment was not opened until well after submission of the NDA, and no patients had been enrolled as of September 2022.
 - 111. Jeanne Fourie Zirkelbach, Ph.D., ⁷ stated the following:

When FDA reviewed the top-line data in 2020 and 2021, we reiterated our concerns regarding efficacy, safety, dose selection, and the delay of confirmation of benefit. In an effort to accelerate the confirmatory trial, [Spectrum] moves forward with a different dosage of 8 milligrams twice daily for their randomized trial, however, FDA continued to reiterate the need for additional data to support the proposed dosage.

Initiating the trial absent these data was at [Spectrum's] risk. Clinical data at the proposed dosage show that poziotinib has marginal activity with a high rate of toxicity. Limited data available are available for other dosages, and it is uncertain if alternative dosages can maintain effectiveness and improve tolerability, therefore, additional dosage optimization is still warranted. As of today, FDA's clinical pharmacology team does not have sufficient information to determine the optimal poziotinib dosage.

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⁷ Dr. Zirkelbach was a Team Lead, Clinical Pharmacology, Division of Cancer Pharmacology 2, Office of Clinical Pharmacology, Office of Translational Sciences, CDER.

(Emphasis added).

112. Harpreet Singh, M.D.,⁸ stated the following:

Dr. Fourie Zirkelbach did state in her presentation, let me reiterate, we did not come to any formal agreement about the 8-milligram BID dose. It's very limited data, and we told [Spectrum] that it would be at their own risk to move forward with this incongruent dose. The safety ER analysis, exposure-response analysis, conducted by our clinical pharmacologist shows fairly comparable safety profiles between the 8 milligrams twice daily and the 16 milligrams once daily. I think a lot of this speaks to [Spectrum] kind of rushing this development program and trying to take catch-up steps, whereas the steps should have been taken slowly, and methodically, and appropriately early in development. . . .

You know, [Spectrum] keeps talking about how they have amassed the largest database in this rare need []. Thus, I find it unfortunate that **they have missed several opportunities and several steps along the way to optimize this dose.** If they had so many patients with this mutation, they should have moved forward either, or both, to adequately optimize the dose in larger patient cohorts, rather than 3 patients per cohort, as they did, or they should have initiated randomized trials. **This is a fatal [] flaw in this development program**, and we really needed to show this data in a different way.

(Emphasis added).

113. Dr. Pazdur stated the following:

what this really represents is poor drug development. Obviously, before somebody launches a large phase 3 trial, they should have confidence in what their dose is, and the dose optimization should occur beforehand.

What would we do if the large phase 3 trial -- if it can accrue, and that's a big if -- is negative? Is it because they chose the wrong dose? We have a whole program here at the FDA on dose optimization, and this just points to one of the problems that we have here when one attempts to launch a phase 3 study without adequately looking at what the dose is and having confidence in it.

I said this before, and I'll say it again. Proceeding with a drug development program when you don't have a well-founded dose is literally building a house on quicksand here, and this is one of the problems.

(Emphasis added).

114. During the ODAC meeting, a member of the ODAC panel (a clinical

⁸ Dr. Singh was Director, DO2, OOD, OND, CDER.

investigator/thoracic oncologist from the National Cancer Institute) asked Defendant Lebel "[i]s the confirmatory trial really underway? . . . the FDA documents seem to indicate that it's much delayed, but [your] discussion seems to suggest it's well under way, although patients are not enrolled. Where is that at this point?"

- 115. In response, Defendant Lebel stated "this study is very much underway, and we acknowledge there are no patients right now . . . we never expected patients at this stage, and we're on track." (Emphasis added).
- 116. Defendant Lebel's statement that Defendants did not expect patients at this stage and that Spectrum was on track was met with incredulity, in light of the fact that since before the Class Period, the FDA had raised concerns about the delayed enrollment in the PINNACLE Study, and the FDA had reiterated the importance of the PINNACLE Study being substantially enrolled by November 24, 2022.
 - 117. Specifically, Dr. Pazdur responded as follows:

[Spectrum] might be happy; we're not, and let me make this real clear.

The issue here is we want companies to come in and have a comprehensive discussion with us very early on regarding what their plans are for accelerated approval and what their plans are to confirm their study. FDA guidance, that has been there for more than a decade, clearly states that it is anticipated that these trials should be ongoing, and by ongoing, we mean accrual of patients to the study at the time of the accelerated approvals

... the point that we want to get across is that we want early discussions on these trials and them to be ongoing, and it's really only fair to the patients because you're really putting patients significantly at risk, and you're also putting your development program at risk because many times response rates will not really project what the true benefit of the drug is, and that will only be seen with a randomized study that looks at overall survival.

In other words, these response rates may not be good correlates or surrogates for overall survival, so you could actually be abandoning drugs just looking at response rates.

But the point I want to get across is really we'd want to have these trials ongoing, and it really is to the detriment of patients not to have these trials ongoing, and this has been in the FDA guidance for many months.

We took a look at this. If one takes a look at the accelerated approvals over the past three or four years, probably 85 percent of these accelerated approvals have ongoing trials. So industry has heard us loud and clear, and this trial is obviously - or this application is not consistent with many of the current trends that we're seeing with other sponsors

(Emphasis added).

118. Also, on September 22, 2022, the ODAC panel voted 9-4 that the benefit of pozi did not outweigh its risks, a recommendation that the FDA not approve the Pozi NDA, and Spectrum issued a press release concerning the FDA ODAC's meeting that stated the following:

SPECTRUM PHARMACEUTICALS PROVIDES AN UPDATE ON POZIOTINIB FOLLOWING FDA ONCOLOGIC DRUGS ADVISORY COMMITTEE MEETING

Spectrum . . . announced that [ODAC] met to review poziotinib for the treatment of patients with previously treated locally advanced or metastatic non-small cell lung cancer ("NSCLC") harboring HER2 exon 20 insertion mutations. The committee voted 9-4 that the current benefits of poziotinib did not outweigh its risks.

- 119. As a result of this news, on September 23, 2022, when trading in shares of Spectrum common stock resumed on Nasdaq, the stock fell again from a closing price on September 21, 2022 of \$0.63 per share (before trading was halted) to close at \$0.43 per share on September 23, 2022, a decrease of \$0.20 per share or approximately 31% on heavier than usual volume.
- 120. On November 25, 2022, Spectrum issued a press release disclosing that the Company received a CRL from the FDA indicating the poziotinib NDA could not be approved in its present form and that the Company would "deprioritize" development of pozi.
- 121. Effective December 31, 2022, Defendant Lebel resigned as EVP and CMO of Spectrum.

VI. DEFENDANTS' FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

- 122. During the Class Period, Defendants' representations to investors were materially false and misleading at the time they were made, and Defendants failed to disclose material facts that they had a duty to disclose in order to make the statements made by Defendants, in light of the circumstances under which they were made, not misleading.⁹
- 123. On March 17, 2022, Defendants Riga and Lebel caused Spectrum to issue a press release titled "Spectrum Pharmaceuticals Reports Fourth Quarter 2021 and Full Year 2021 Financial Results and Corporate Update", and Defendants Defendant Riga and Lebel participated in an earnings call with analysts and investors. During the conference call with investors and analysts, an analyst asked Defendants Riga and Lebel "how should we be thinking about a potential label in second line? Is there the possibility of getting the 8-milligram BID dosing? Or are you thinking it has to be 16-milligram to start?" Defendant Riga responded as follows:

So you know that the Cohort 2 was dosed at 16 milligrams QD and through Cohort 5 and a number of the work that we've done have produced a pretty healthy body of evidence in the BID setting. So we'll wait and see until the label negotiation part of the discussion with the agency occurs. But we are seeing that 16 QD is certainly a safe and effective dose. And I think over time, we have learned to optimize some of the tolerability and abate some of the AEs [(adverse events)] here with the BID dosage. So I think that will be a key topic when we get to label negotiations with the agency, and we're simply not at that point of the review cycle, which will be coming here shortly.

124. Defendant Riga's representation that Spectrum had "learned to optimize some of the tolerability and abate some of the AEs here with the BID dosage" was materially false and misleading at the time he made it, and he failed to disclose material facts that he had a duty to

⁹ In Section VI, Defendants' false and misleading statements are identified in bold typeface, and other statements are included to provide context and to demonstrate the materially false and misleading nature of Defendants' representations, and Defendants' material omissions.

¹⁰ Federal regulations require FDA-approved drugs to include information concerning the drug's approved dosage on the drug's label. 21 C.F.R. § 201.57.

disclose in order to make the statements made by him, in light of the circumstances under which they were made, not misleading because Defendant Riga's representations created the false impression that Spectrum had adequate data to "optimize" the BID dose for pozi, when in fact, the FDA had informed Defendants Riga and/or Lebel that this was not true. During meetings with Defendants Lebel and/or Riga before the Class Period, the FDA repeatedly told Defendants Lebel and/or Riga that Spectrum's dose optimization data were inadequate for both the 16 mg QD and 8 mg BID doses, that additional data and studies were needed to determine whether Defendants' dose selection for pozi was optimized, and that Spectrum had not optimized the dosage for pozi for further evaluation in the PINNACLE Study at 8 mg BID.

125. On May 12, 2022, Defendants Riga and Lebel caused the Company to issue a press release titled "Spectrum Pharmaceuticals Reports First Quarter 2022 Financial Results and Provides Corporate Update" (the "May 12 Press Release") that stated the following:

A study for poziotinib has been initiated to confirm the clinical benefit seen in Cohort 2, as required for an accelerated approval. The trial, Study SPI-POZ-301 (PINNACLE), is designed to enroll 268 patients with previously treated NSCLC harboring HER2 exon 20 mutations. Patients are being randomized 2-to-1 into one of two treatment arms using 8mg of poziotinib orally administered BID (twice daily) versus 75mg/m2 of docetaxel administered intravenously every three weeks. The primary endpoint will be Progression Free Survival.

126. Also on May 12, 2022, Spectrum hosted an earnings call with analysts and investors. Defendant Riga and Lebel participated on behalf of Spectrum and Defendant Lebel repeated the representations in the May 12 Press Release as follows:

We believe poziotinib has the potential to be the first to market for this specific indication, an area of great unmet medical need. We now have initiated a randomized confirmatory study following discussion with the FDA and are operat[ing] with a great sense of urgency. Study SPI-POZ-301 or PINNACLE is designed to enroll 268 patients with previously treated non-small cell lung cancer, harboring HER2 exon 20 mutation. Patients are being randomized 2:1 into this global multicenter study to receive 8-milligram of pozi-administered BID versus 75-milligram per meter square of docetaxel-administered IV every 3 weeks.

- 127. Defendant Riga and Lebel's representations that "patients are being randomized" into the PINNACLE Study were materially false and misleading at time the they made them, and they failed to disclose material facts that they had a duty to disclose in order to make the statements made by them, in light of the circumstances under which they were made, not misleading because, in fact, as of May 12, 2022 the PINNACLE Study had not enrolled any patients.
- 128. Also during the May 12, 2022 earnings call, an analyst asked Defendants Riga and Lebel "between now and ODAC, how much will we learn from your ongoing studies? And what might be the data you are able to present to the panel on the 8 mg? And how do you reconcile a full approval in a different dose with the [accelerated] approval with a sort of different dosing schedule?" Defendant Riga responded as follows:

So the registrational -- the filing [(the Pozi NDA)] is based on Cohort 2. As you mentioned, the 16 milligrams given QD, and the PMR [post marketing requirement] is at 8-milligrams BID ([the PINNACLE Study)]. So both are 16-milligrams per day. We believe that 16-milligrams QD demonstrated a safe and effective dose for a patient population that needs a solution.

I think the subsequent data has given an indication that there could be a more optimal way to reduce some of the on-target toxicities. So I think that the conundrum that you mentioned is likely a topic that FDA would like to hear from industry experts at the ODAC panel. But we believe that 16 QD is a safe and effective dose and obviously aligned with FDA on the confirmatory study to go with the 8-milligram BID....

obviously aligned with FDA on the confirmatory study to go with the 8-milligram BID" was materially false and misleading at the time it was made, and he failed to disclose material facts that he had a duty to disclose in order to make the statements made by him, in light of the circumstances under which they were made, not misleading because, far from being "aligned with FDA" on the 8 mg BID dose for the design of the PINNACLE Study, the FDA told Defendants Riga and/or Lebel during meetings before the Class Period that Spectrum's dose optimization data were

inadequate, that additional data and studies were needed to determine whether Defendants' dose selection for pozi was optimized, that Spectrum had not optimized the dosage for pozi for further evaluation in the PINNACLE Study at 8 mg BID, that the FDA did not agree on the design of the PINNACLE Study design to treat patients at 8 mg BID due to Spectrum's inadequate dose optimization data, and warned Defendants Riga and/or Lebel, in light of the FDA's concerns about the dosing, efficacy and safety data, that proceeding with the 8 mg BID dose in the PINNACLE Study was at their own risk.

130. Also on the May 12, 2022 earnings call, an analyst asked Defendants Riga and Lebel, in reference to the confirmatory trial, "regarding the ODAC meeting. I just wanted to get your thoughts on maybe what preparations are you doing? What are you expecting the advisory committee to ask?" Defendant Riga responded, in pertinent part:

So here's how we're thinking about it. We're looking forward to the opportunity to bring this to an advisory committee and really share the full benefit that pozi could bring in this high area of unmet need. So if you think about even at the acceptance, we had made some statements that the FDA had questions about the status of the confirmatory study as well as questions on the dose. And today, we announced the PINNACLE study which has a dose of 8-milligrams BID, which is different than the 16-milligram QD registrational data.

So it's, for us, very -- it makes a lot of sense. It's very logical that **the FDA could have additional questions on dosing** and wanting to hear from industry experts on how to bring that issue to resolution. But that's us looking at where we've been, what the discussions have been with the agency, those are two of the issues that certainly could be discussed at ODAC. But as the date gets closer, we will gain more clarity from FDA, and obviously, be prepared to represent the full NDA.

So our preparation efforts are -- the last half of your question, they're under -- they're actively underway. We think we've got the right team in place to prepare, and are looking forward to the opportunity.

131. Defendant Riga's representation that the "the FDA could have additional questions on dosing" was materially false and misleading at the time it was made, and he failed to disclose material facts that he had a duty to disclose in order to make the statements made by him, in light

of the circumstances under which they were made, not misleading because Defendant Riga knew, or recklessly disregarded, that Spectrum's dosing data was the sticking point for the FDA at that point in time and the FDA had unanswered questions and ongoing concerns about Defendants' dose optimization data that as of May 12, 2022 Spectrum had not addressed to the satisfaction of the FDA. Defendant Riga knew, or recklessly ignored, that the FDA told Defendants Riga and/or Lebel during meetings before the Class Period that Spectrum's dose optimization data were inadequate, that additional data and studies were needed to determine whether Defendants' dose selection for pozi was optimized, that Spectrum had not optimized the dosage for pozi for further evaluation in the PINNACLE Study at 8 mg BID, that the FDA did not agree on the design of the PINNACLE Study design to treat patients at the 8 mg BID dose due to Spectrum's inadequate dose optimization data, and warned Defendants, in light of the FDA's concerns about the dosing, efficacy and safety data, that proceeding with the 8 mg BID dose in the PINNACLE Study was at their own risk.

132. Defendant Riga and Lebel's misrepresentations on May 12, 2022 created a false impression that the PINNACLE Study was enrolling patients and that the Company and the FDA were aligned on the design of the PINNACLE Study, and that Spectrum was on track to substantially enroll patients in the PINNACLE Study by November 24, 2022, none of which was true. Indeed, in a May 13, 2022 research report, Jefferies reported that Spectrum "announced alignment w/FDA on confirmatory ph.III [] design, which will assess pozi 8mg BID in [second-line] HER2 exon20 NSCLC w/primary [endpoint median progression free survival]; the confirmatory study is an important moving part, b/c FDA has iterated the importance of having the confirmatory trial 'substantially enrolled' by the time of approval." On May 16, 2022, JMP published a research report that showed that Defendants' misrepresentations that "patients are

being randomized" into the PINNACLE Study created the false impression that patients were enrolling in the PINNACLE Study, when, in fact, no patients had enrolled as of May 12, 2022: "[i]n preparation for the approval, Spectrum noted that it has started enrolling patients in a confirmatory trial, SPI-POZ-301 (PINNACLE), which needs to be substantially enrolled by the time of the approval."

133. On May 12, 2022, Defendant Riga caused the Company to file its quarterly report for the quarter ended March 31, 2022 with the SEC on Form 10-Q ("Q1 2022 10-Q"). The Q1 2022 10-Q, which was signed by Defendant Riga, incorporated by reference purported warnings about future risks stated in the 2021 10-K (which was filed in March 2022), as follows:

We are currently conducting multiple clinical trials for our products . . . The commencement and completion of these clinical trials **may be delayed** by various factors, including . . . difficulties in identifying and enrolling patients who meet trial eligibility criteria

Moreover, the commencement and completion of clinical trials **may be delayed** by many factors that are beyond our control, including: . . . slower than anticipated patient enrollment or our inability to recruit and enroll patients to participate in clinical trials for various reasons

- 134. Defendant Riga's warning of potential future risks were materially false and misleading at the time they were made, and he failed to disclose material facts that he had a duty to disclose in order to make the statements made by him, in light of the circumstances under which they were made, not misleading, because the stale, hypothetical and generic risk warning that clinical trials "may be delayed" had already materialized and was negatively affecting the Company at that time. In fact, as of May 12, 2022, contrary to Defendants' representations and warning that clinical trials may be delayed, no patients had enrolled in the PINNACLE Study and the FDA had repeatedly expressed concerns to Defendants Riga and/or Lebel about the delays in enrollment in the PINNACLE Study.
 - 135. Item 303 of SEC Regulation S-K, 17 C.F.R. 929.303 ("Item 303") required the Q1

2022 10-Q's Management Discussion and Analysis ("MD&A") section to disclose known uncertainties that are reasonably likely to have a material unfavorable impact on the Company's net sales or revenues or income from continuing operations. Defendant Riga knew, or at least recklessly disregarded, that the FDA informed Defendants Riga and/or Lebel that Spectrum's dose optimization data were inadequate and that additional data and studies were required to determine the optimal dose, that the Company and the FDA did not agree on the design of the PINNACLE Study to treat patients with pozi at the 8 mg BID dose and that the FDA warned that Spectrum was proceeding at its own risk, and that Spectrum had failed to enroll any patients in the PINNACLE Study as of May 12, 2022, all of which were known material uncertainties that were reasonably likely to have a material unfavorable impact on pozi's commercial value, and ultimately did have a material unfavorable impact on the Company's net sales, revenues, and income.

- 136. On June 16, 2022, Defendants Riga and Lebel participated in the JMP Securities Life Sciences Conference in New York City during which Defendant Riga represented that Spectrum was on "the cusp of not just one, but two FDA approvals with the action dates in the next five months."
- 137. Defendant Riga's representation to investors that Spectrum was "on the cusp" of FDA approval created the misleading impression that the Pozi NDA was on the verge of FDA approval. However, far from being on the cusp or verge of AA for the Pozi NDA, as of June 16, 2022, Defendant Riga knew of, or at least recklessly ignored, material negative facts and the FDA's expressed concerns about the pozi NDA that contradicted his positive representation: as of June 16, 2022, no patients had enrolled in the PINNACLE Study, which was designed to enroll 268 patients and which the FDA required to be substantially enrolled by November 24, 2022, and just weeks before Defendant Riga's representations, during a May 18, 2022 meeting, Defendants Riga

and/or Lebel were again told of the FDA's ongoing concerns about Spectrum's inadequate dose optimization data, its concerns about pozi's efficacy and safety, and delays in the enrollment in the PINNACLE Study. Indeed, at the May 18, 2022 meeting, the FDA informed Defendants Riga and/or Lebel that "uncertainties remain" regarding whether the proposed dosage of 16 mg QD, which is what was being sought for AA in the Pozi NDA, was optimized from both the efficacy and safety perspectives. Accordingly, Defendant Riga had no reasonable basis in fact to represent to investors that the Pozi NDA was on the cusp of approval.

138. On August 11, 2022, Defendants Riga, Lebel and Brennan caused Spectrum to issue a press release titled "Spectrum Pharmaceuticals Reports Second Quarter 2022 Financial Results and Provides Corporate Update" that stated the following:

A study for poziotinib is in progress to confirm the clinical benefit seen in Cohort 2, as required for accelerated approval. The trial, Study SPI-POZ-301 (PINNACLE), is designed to enroll 268 patients with previously treated NSCLC harboring HER2 exon 20 mutations. Patients are being randomized 2-to-1 into one of two treatment arms using 8mg of poziotinib orally administered BID (twice daily) verses 75mg/m2 of docetaxel administered intravenously every three weeks. The primary endpoint is progression free survival.

- 139. Defendants Riga, Lebel and Brennan's representations to investors were materially false and misleading at the time they were made, and they failed to disclose material facts that they had a duty to disclose in order to make the statements made by them, in light of the circumstances under which they were made, not misleading because as of August 11, 2022 no patients had in fact enrolled in the PINNACLE Study.
- 140. On August 11, 2022, Spectrum hosted an earnings call with analysts and investors, in which Defendants Riga, Lebel and Brennan participated. Defendant Lebel made the following statements:

Our randomized [confirmatory] study is underway. We have leveraged our team with the extensive experience of PPD, one of the largest international CRO, to conduct the study in as many as 20 countries targeting up to 150 sites. I just returned

from the World Lung Cancer meeting, where we had multiple interaction with highly interested international investigators.

We look forward to continuing our active engagement with investigators at the ESMO upcoming meeting. Study 301 or PINNACLE is designed to enroll 268 patients with previously-treated non-small cell lung cancer harboring HER2 exon 20 mutations. Patients are being randomized 2:1 into this global multicenter study to receive 8 milligram of pozi administered BID versus 75 milligram per meter square of docetaxel administered IV every 3 weeks. Patient will be evaluated at week 6 and every 6 weeks thereafter. Following progression on docetaxel, patient will be allowed to cross over to be pozi arm. The primary endpoint is progression-free survival with OS, ORR, duration of response and disease control rates, and safety as secondary objectives. This design will provide a power of 95% to test the hypothesis that pozi is superior to docetaxel for a hazard ratio of equal or smaller than 0.5 days using 2 sided logrank test.

- 141. Defendants Lebel's representation to investors that "patients are being randomized" in the PINNACLE Study was materially false and misleading at the time it was made, and he failed to disclose material facts that he had a duty to disclose in order to make the statements made by him, in light of the circumstances under which it was made, not misleading because as of August 11, 2022 no patients had in fact enrolled in the PINNACLE Study.
- 142. Also on the August 11, 2022 earnings call an analyst asked Defendants Riga, Lebel and Brennan "a follow-up on pozi. So maybe on the confirmatory Phase III, how many sites are active right now? What percentage of your target patients have been enrolled in Phase III? And where do you need to be on enrollment to satisfy FDA's focus on substantial enrollment by PDUFA date?" The following colloquy ensued:

[Defendant Lebel:] So we're -- again, were very active in opening site. But as I'm sure you know, it takes a long time to open sites. We have some site open. I'm not going to give you numbers today. I'm not going to speak directly to enrollment today. And so we're moving as fast as we can internationally as well as in North America. So I can't remember -- the second part of your question was what?

[Analyst:] Where do you need to be on enrollment to satisfy on FDA's substantial enrollment or PDUFA [date].

[Defendant Lebel:] So we have discussed directly with the agency if there was a particular threshold that we had to achieve by PDUFA da[te] and the

information we got from the [agency is] that this would be a multifactorial judgment that there's not a single number that one has to achieve and that we believe that on the basis of that discussion is that we have to demonstrate a true active program here that as you know, over the years, the last few years, the number of companies maybe were not quite as serious as they probably had to be, and we believe that we will be able to show unequivocally that we are taking this commitment very seriously and are moving forward as fast as we can.

Defendants Lebel's representations to investors were materially false and misleading at the time they were made, and he failed to disclose material facts that he had a duty to disclose in order to make the statements made by him, in light of the circumstances under which they were made, not misleading because at that time Defendant Lebel knew, or at least recklessly disregarded, that the FDA had repeatedly expressed concerns about pozi's efficacy, safety and lack of adequate dosing optimization data and informed Defendants Lebel and/or Riga that additional data and studies were required to optimize the pozi dosage, that Spectrum and the FDA did not agree on the design of the PINNACLE Study and that Defendants were pressing forward in the face of being told by the FDA that they were proceeding at their own risk, and that as of August 11, 2022 no patients had enrolled in the PINNACLE Study. Furthermore, Defendant Lebel's representations about his discussions with the FDA concerning enrollment in the PINNACLE Study and his statement "that there's not a single number that one has to achieve", was false and misleading because he created the false impression that, while the FDA may not have required a specific number of patients to be enrolled by November 24, 2022 (the PDUFA date), Spectrum, as of August 11, 2022, had and was continuing to enroll patients in the PINNACLE Study and that Spectrum was on track for the PINNACLE Study to be substantially enrolled by November 24, 2022 as required by the FDA, when, in fact, as of August 11, 2022 no patients had enrolled in the PINNACLE Study and the FDA had repeatedly expressed concerns about the delayed enrollment in the PINNACLE Study.

144. Defendant Lebel's misrepresentations concerning the status of patient enrollment

in the PINNACLE Study misled investors. On August 12, 2022, H.C. Wainwright published a report concerning Spectrum that stated "the PINNACLE study utilizing 8 mg BID bodes well for the potential approval," when, in fact, it did not bode well. Unknown to investors, Spectrum and the FDA had not agreed on the design of the PINNACLE Study utilizing the 8 mg BID dose due to the FDA's ongoing concerns that Spectrum lacked adequate dose optimization data and, in light of Spectrum's inadequate dose optimization data, the FDA warned Defendants that they were proceeding with the PINNACLE Study at their own risk, and as of August 12, 2022, no patients had enrolled in the PINNACLE Study.

- 145. On August 12, 2022, Defendants Riga, Lebel and Brennan caused the Company to file its quarterly report for the quarter ended June 30, 2022 with SEC on form 10-Q ("Q2 2022 10-Q). Defendant Riga certified that he reviewed Q2 2022 10-Q and the Q2 2022 10-Q was signed by Defendant Brennan. The Q2 2022 10-Q repeated the purported risk warnings set forth in paragraph 133.
- 146. Defendants Brennan and Riga's representations to investors were materially false and misleading at the time they were made, and they failed to disclose material facts that they had a duty to disclose in order to make the statements made by them, in light of the circumstances under which they were made, not misleading because the stale, hypothetical and generic future risk warned of—that clinical studies "may be delayed"—had already materialized and was then negatively affecting the Company, and as of August 12, 2022, no patients had enrolled in the PINNACLE Study.
- 147. Item 303 required the Q2 2022 10-Q's MD&A section to disclose known uncertainties that are reasonably likely to have a material unfavorable impact on the Company's net sales or revenues or income from continuing operations. Defendants Riga and Brennan knew,

or at least recklessly disregarded, that the FDA informed Defendants Riga and/or Lebel that Spectrum's dose optimization data were inadequate and that additional data and studies were required to determine the optimal dose, that the Company and the FDA did not agree on the design of the PINNACLE Study to treat patients with pozi at the 8 mg BID dose and that the FDA warned that Spectrum was proceeding at its own risk, and that Spectrum had failed to enroll any patients in the PINNACLE Study as of August 12, 2022, all of which were known material uncertainties that were reasonably likely to have a material unfavorable impact on pozi's commercial value, and ultimately did have a material unfavorable impact on the Company's net sales, revenues, and income.

VII. LOSS CAUSATION

- 148. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the prices of Spectrum common stock and operated as a fraud or deceit on purchasers of Spectrum common stock. As detailed above, when the truth about Spectrum's misconduct was revealed, the value of the Company's stock declined precipitously as the prior artificial inflation no longer inflated the stock's prices. The decline in the price of Spectrum shares were the direct result of the nature and extent of Defendants' fraud finally being revealed to investors and the market.
- 149. The timing and magnitude of the share price declines negate any inference that the losses suffered by Plaintiff and other members of the Class were caused by changed market conditions, macroeconomic or industry factors, or Company specific facts unrelated to the Defendants' fraudulent conduct.
- 150. The economic loss, *i.e.*, damages, suffered by Plaintiff and other Class members, was a direct result of Defendants' fraudulent scheme to artificially inflate the prices of the Company's stock and the subsequent significant decline in the value of the Company's stock when

Defendants' prior misrepresentations and other fraudulent conduct were revealed.

151. At all relevant times, Defendants' materially false and misleading statements or omissions alleged herein directly or proximately caused the damages suffered by the Plaintiff and other Class members. As alleged with particularity in Section VI, throughout the Class Period, Defendants made materially false and misleading statements and omitted material facts necessary to make Defendants' statements not false or misleading, causing the price of Spectrum's common stock to be artificially inflated. Plaintiff and other Class members purchased Spectrum stock at those artificially inflated prices, causing them to suffer damages when Defendants' fraud was revealed and the price of Spectrum shares declined.

VIII. ADDITIONAL SCIENTER ALLEGATIONS

- 152. During the Class Period, Defendants had actual knowledge of the materially false and misleading nature of the statements they made, or at least acted in reckless disregard of the true information known to them at the time. In so doing, Defendants participated in a scheme to defraud and committed acts, practices, and participated in a course of business that operated as a fraud or deceit on purchasers of Spectrum common stock during the Class Period. The scienter of senior executives and officers of Spectrum, including Defendants Riga, Lebel and Brennan, who acted within the scope of their authority and as agents of Spectrum, is imputed to corporate Defendant Spectrum.
- 153. During the Class Period, Defendants had both the motive and opportunity to conduct fraud. Defendants were motivated to commit the acts alleged herein in order to inflate the price of Spectrum common stock and sell Spectrum common stock at artificially inflated prices.
- 154. Through sales under the April 2019 ATM Agreement throughout the Class Period, Defendants Riga and Brennan caused Spectrum to sell at least 10.7 million shares of Spectrum common stock for proceeds of approximately \$9.4 million.

- the Class Period (each a "Placement"), Defendants Riga and Brennan in their respective capacities as principal financial officer of the Company, notified the New York City-based employees or agents of Cantor Fitzgerald, H.C. Wainwright & Co., or B. Riley by email notice (or other method mutually agreed to by them) of the number shares to be issued, the time period during which sales were requested to be made, any limitation on the number of shares to be sold and any minimum price below which sales would not be made (a "Placement Notice"). During the Class Period, the Placement Notices originated from Defendant Riga and Brennan, with approval of the Company's board, including any committees of the Spectrum Board, such as the Placement Committee. According to the Company's SEC filings, the Company's CEO was a member of the Placement Committee and the Placement Committee possessed the authority to act on behalf of Spectrum's board with respect to approving and evaluating all issuances of Spectrum securities (other than relating to compensation), including the authority to set the terms of each security being issued.
- NDA and the PINNACLE Study without the dose optimization data required by the FDA and mislead investors because Spectrum was in a precarious financial condition and needed to raise cash. Spectrum was on track to run out of cash by the end of 2022. As of December 31, 2021, Spectrum reported cash, cash equivalents and marketable securities of approximately \$100 million and had reported spending at least \$25 million per quarter (with no revenue from commercial sales). During the Class Period, Spectrum issued a going concern warning.
- 157. None of the Individual Defendants purchased Spectrum common stock on the open market, and Defendants Lebel and Brennan sold shares of Spectrum common stock as set forth below at artificially inflated prices:

- a. On April 4, 2022, Defendant Lebel sold 1,205 shares of Spectrum common stock at a price of \$1.35 per share, for proceeds of approximately \$1,626.75.
- b. On April 5, 2022, Defendant Lebel sold 1,367 shares of Spectrum common stock at a price of \$1.41 per share, for proceeds of approximately \$1,927.47.
- c. On June 21, 2022, Defendant Brennan sold 3,569 shares of Spectrum common stock at a price of \$0.79 per share, for proceeds of approximately \$2,819.51.
- d. On June 22, 2022, Defendant Lebel sold 6,096 shares of Spectrum common stock at a price of \$0.81 per share, for proceeds of approximately \$4,937.76.
- e. On June 23, 2022, Defendant Lebel sold 6,667 shares of Spectrum common stock at a price of \$0.84 per share, for proceeds of approximately \$5,600.28.

IX. NO SAFE HARBOR

- 158. The materially false and misleading statements alleged in Section VI were not forward-looking, but rather were historic or present tense representations of facts. Accordingly, any "Safe Harbor" warnings are inapplicable.
- 159. Assuming *arguendo*, any of Defendants' representation were forward-looking statements ("FLS"), Spectrum's "Safe Harbor" warnings accompanying any such FLS issued during the Class Period were ineffective to shield those statements from liability.
- 160. Defendants are liable for any false or misleading FLS pleaded herein because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of Spectrum who knew that the FLS was false. None of the historic or present tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic

performance when made, nor were any of the projections or forecasts made by Defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

- 161. In addition, the FLS were contradicted by existing, undisclosed material negative facts that were required to be disclosed so that the FLS would not be misleading.
- 162. Finally, Defendants' "Safe Harbor" warnings were themselves misleading because they warned of "risks" that could or might occur, but that had already materialized or failed to provide any meaningful disclosures of the relevant risks.

X. APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET

- 163. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:
 - (a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
 - (b) The omissions and misrepresentations were material;
 - (c) The Company's common stock traded in an efficient market;
 - (d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and
 - (e) Plaintiff and other members of the Class purchased Spectrum common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.
- 164. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972).

Here, the Class' claims are also grounded on Defendants' failure to disclose the material, adverse concerns the FDA had concerning Cohort 2 study data results and the efficacy, safety, and dosing optimization data for pozi, delays in the PINNACLE Study and that not a single patient enrolled, and that the FDA and the Company were not aligned on the design of the PINNACLE Study—information that the Defendants should have disclosed and proof that positive reliance is not a prerequisite to recovery. Instead, the withheld facts must be material in the sense that a reasonable investor may have considered them important in making investment decisions. Based on the alleged omissions herein, this requirement is satisfied here.

- 165. At all relevant times, the market for Spectrum common stock was efficient for the following reasons, among others:
 - (a) As a regulated issuer, Spectrum filed periodic public reports with the SEC;
 - (b) The Company's shares traded on NASDAQ, an efficient market;
 - (c) Defendants regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and investors, and other similar reporting services;
 - (d) The Company was covered by research analysts, including Jefferies, Cantor Fitzgerald, H.C. Wainwright, JMP, and B. Riley; and
 - (e) Spectrum was eligible to file a Form S-3 Registration Statement under the Securities Act of 1933 with the SEC, and, in fact, had filed a Registration Statement on Form S-3 on July 13, 2021.

XI. CLASS ACTION ALLEGATIONS

166. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules

of Civil Procedure on behalf the Class. Excluded from the Class are Defendants, current and former directors and officers of Spectrum, and their families and affiliates. The members of the Class are so numerous that joinder of all members is impracticable.

- 167. The disposition of Class members' claims in a class action will provide substantial benefits to the parties and the Court. Spectrum had more than 177 million shares of common stock outstanding as of March 10, 2022 and more than 188 million shares outstanding as of August 8, 2022.
- 168. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:
 - (a) Whether the Exchange Act was violated by Defendants;
 - (b) Whether Defendants omitted and/or misrepresented material facts;
 - (c) Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
 - (d) Whether Defendants knew, or disregarded with at least recklessness, that their statements were false and misleading at the time they were made;
 - (e) Whether the price of Spectrum common stock was artificially inflated; and
 - (f) The extent of damage sustained by Class members and the appropriate measure of damages.
- 169. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct.
 - 170. Plaintiff will adequately protect the interests of the Class and has retained counsel

(Kaplan Fox) who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

171. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

XII. CAUSES OF ACTION

COUNT I For Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

- 172. Plaintiff incorporates paragraphs 1-171 by reference.
- 173. During the Class Period, Defendants disseminated or approved the false and misleading statements specified above, which they knew were false and misleading, or at least recklessly disregarded that they were false and misleading, because they contained misrepresentations or failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.
 - 174. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they:
 - (a) Employed devices, schemes, and artifices to defraud;
 - (b) Made untrue statements of material fact or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
 - (c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Plaintiff and others similarly situated in connection with their purchases of Spectrum common stock during the Class Period.
- 175. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Spectrum common stock. Plaintiff and the Class would not have purchased Spectrum common stock at the prices they paid, or at all, if they had

been aware that the market prices had been artificially and falsely inflated by Defendants' false and misleading statements.

176. As a direct and proximate result of these Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchases of Spectrum common stock during the Class Period.

COUNT II For Violation of Section 20(a) of the Exchange Act Against the Individual Defendants

- 177. Plaintiff incorporates paragraphs 1-171 by reference.
- 178. The Individual Defendants each acted as a controlling person of Spectrum within the meaning of Section 20 of the Exchange Act. By virtue of their respective positions as senior executives and/or directors of the Company and their power to control public statements to investors about Spectrum, which they exercised throughout the Class Period, the Individual Defendants had the power and ability to control the actions of Spectrum and its employees.
- 179. By reason of such conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act.

XIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

- A. Declaring this action to be a proper class action under Rule 23 of the Federal Rules of Civil Procedure, certifying Plaintiff as class representative, and appointing Plaintiff's counsel as class counsel;
 - B. Awarding Plaintiff and the members of the Class damages and interest;
 - C. Awarding Plaintiff reasonable costs, including attorneys' fees; and
- D. Awarding such equitable injunctive or other relief as the Court may deem just and proper.

XIV. JURY DEMAND

Plaintiff demands a trial by jury.

Dated: May 26, 2023

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Lead Counsel for Lead Plaintiff Steven B. Christiansen, and the Proposed Class

CERTIFICATION

- I. Steven B. Christiansen, hereby certify as follows:
- I have reviewed the Consolidated Class Action Complaint for Violations of the Federal Securities Laws (the "Amended Complaint") and authorize the filing of the Amended Complaint.
- I did not purchase the securities that are the subject of this action at the direction of plaintiff's counsel or in order to participate in any private action arising under the federal securities laws.
- I am willing to serve as a representative party on behalf of a class, including providing testimony at deposition and trial if necessary.
- My transactions in Spectrum Pharmaceuticals, Inc. common stock during the 4. proposed class period alleged in the Amended Complaint, are set forth in the Schedule A. attached hereto.
- Other than this action, I have not sought to serve as a representative party on behalf of a class in any action under the federal securities laws filed during the three-year period preceding the date of this Certification.
- I will not accept any payment for serving as a representative party on behalf of a 6. class beyond my pro-rata share of any recovery, except as ordered or approved by the court, including any award to a representative plaintiff of reasonable costs and expense directly related to the representation of the class.

7. I declare under penalty of perjury that the foregoing is true and correct, executed on $\frac{5}{22}/\frac{2023}{}$

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SCHEDULE A

Steven B. Christiansen's Transactions in Spectrum Pharmaceuticals, Inc. Common Stock

| Security Description | CUSIP | Transaction | Date | Quantity | Price |
|---|-------------|-------------|-----------|----------|--------|
| Account 1: | | | | | |
| Spectrum Pharmaceuticals, Inc. | 84763A108 | Sold | 3/17/2022 | (39,990) | \$0.80 |
| Spectrum Pharmaceuticals, Inc. | 84763A108 | Bought | 3/30/2022 | 40,000 | \$1.26 |
| Spectrum Pharmaceuticals, Inc. | 84763A108 | Sold | 4/4/2022 | (100) | \$1.44 |
| Spectrum Pharmaceuticals, Inc. | 84763A108 | Sold | 4/4/2022 | (39,900) | \$1.43 |
| Spectrum Pharmaceuticals, Inc. | 84763A108 | Bought | 4/5/2022 | 40,000 | \$1.37 |
| Spectrum Pharmaceuticals, Inc. | 84763A108 | Bought | 4/5/2022 | 10,000 | \$1.35 |
| Spectrum Pharmaceuticals, Inc. | 84763A108 | Bought | 4/6/2022 | 10,000 | \$1.25 |
| Spectrum Pharmaceuticals, Inc. | 84763A108 | Bought | 4/6/2022 | 10,000 | \$1.25 |
| Spectrum Pharmaceuticals, Inc. | 84763A108 | Bought | 4/7/2022 | 10,000 | \$1.23 |
| Spectrum Pharmaceuticals, Inc. | 84763A108 | Bought | 4/11/2022 | 4,155 | \$1.12 |
| Spectrum Pharmaceuticals, Inc. | 84763A108 | Bought | 4/11/2022 | 5,845 | \$1.12 |
| Spectrum Pharmaceuticals, Inc. | 84763A108 | Bought | 4/12/2022 | 10,000 | \$1.06 |
| | 84763A108 | Sold | 8/12/2022 | (28,802) | \$1.43 |
| Spectrum Pharmaceuticals, Inc. Spectrum Pharmaceuticals, Inc. | 84763A108 | Bought | 8/17/2022 | 54,000 | \$1.30 |
| Spectrum Filarmaceuticals, Inc. | 0-170571100 | 200g.iv | | | |
| Account 2: | | | | + | |
| Spectrum Pharmaceuticals, Inc. | 84763A108 | Buy | 5/5/2022 | 9,500 | \$0.85 |
| Spectrum Pharmaceuticals, Inc. | 84763A108 | Buy | 5/6/2022 | 100 | \$0.83 |
| Spectrum Pharmaceuticals, Inc. | 84763A108 | Sell | 8/9/2022 | (1,000) | \$1.04 |
| Spectrum Pharmaceuticals, Inc. | 84763A108 | Sell | 9/12/2022 | (7,712) | \$1.37 |
| Spectrum Pharmaceuticals, Inc. | 84763A108 | Sell | 9/12/2022 | (888) | \$1.38 |